

REMARKS/ARGUMENTS

Following entry of the present Response and Amendment, claims 1-66, and 80-128 remain in this application, with claims 1, 37, 57, and 128 being written in independent format.

In the Office Action dated July 27, 2005 (the "Office Action"), claims 1-5, 10-14, 16-56, 64-66, and 80-115 were rejected as allegedly being indefinite under 35 U.S.C. § 112, second paragraph.

With respect to prior art, the Office Action rejected claims 1-5, 28, 32, 36-39, 41, 42, 44, 50, 55-57, 62-65, 80-83, 88-97, 103-109, 114-120, 126 and 127 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,422,240 to Levitsky et al. (henceforth "Levitsky") in view of U.S. Patent No. 6,439,234 to Curti et al. (henceforth "Curti"). Further, the Office Action rejected claims 16-20 under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 5,626,131 to Chua et al. (henceforth "Chua"). Also, claims 21-26 and 60-61 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 6,467,477 to Frank et al. (henceforth "Frank"). Additionally, claims 33-35 and 52-54 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 5,937,858 to Connell (henceforth "Connell"), while claims 36 and 51 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 5,099,834 to Fishman (henceforth "Fishman"). Finally, the Office Action rejected claims 46-49 and 66 under 35 U.S.C. § 103(a) as allegedly being unpatentable over both Levitsky and Curti in further view of U.S. Patent No. 4,602,644 to DiBenedetto et al. (henceforth "DiBenedetto").

Claims 10-14, 27, 29-31, 40, 43, 45, 59, 84-86, 98-102, 110-113 and 121-125 were indicated as being directed to allowable subject matter, but were objected to in the Office Action only on the basis of being dependent claims referring to rejected independent claims.

In the present Response and Amendment, claims 1, 37, 57, 80, 87-88, 93-96, 98-100, 103, 105-108, 110-112, 114, 116-119, 121-123, and 126 have been amended. New

independent claim 128 has been introduced for examination upon the merits. Claims 1-5, 10-14, 16-66, and 80-128, as amended, still remain in the application. These amendments to the claims have been introduced to clarify the subject matter of the present invention, and to place the present application in better condition for allowance.

Applicant submits that the above-requested amendments do not add prohibited new subject matter, and respectfully requests reconsideration of the merits of the present application in accordance with these amendments and the following remarks.

Claim Rejections

Each of the grounds for claim rejections is addressed below.

35 U.S.C. § 112, second paragraph

Insofar as these two references serve as the underlying grounds for rejection with respect to all of the claims as presently amended, Applicant respectfully traverses as follows.

Applicant submits that all claim rejections under section 112 have been obviated by the amendments to the claims made herein. Specifically, it is believed that all presently pending claims have proper antecedent basis for all limitations and that all dependent claims recite the proper dependency.

Reconsideration and removal of this rejection is thus respectfully requested.

35 U.S.C. § 103(a) – applying Levitsky and Curti

Insofar as these two references serve as the underlying grounds for rejection with respect to all of the claims as presently amended, Applicant respectfully traverses as follows.

Specifically in regard to independent claims 1, 37, 57 as previously presented, the Office Action contends in pertinent part that Levitsky teaches placing an oronasal device having the structure specifically recited by Applicant's claims in an area between a nose and mouth of a person where the cannula device has portions for collecting expired gases from each nostril and from the mouth. The Office Action thereafter purportedly combines Levitsky with Curti to add the limitation that the device also enables the determining of whether the person is inhaling or exhaling and delivering an increased flow of inspired gas to the person

during the inhalation phase.

With regard to claim 37, in support of its incorrect conclusion that Levitsky teaches individual collection of the gases, the Office Action specifically alleges that the nasal and mouth prongs depicted in Levitsky “collect expired gases individually initially prior to converging into a single line.”

As noted above, while the Office Action admits that Levitsky does not teach detecting when a person is inhaling or exhaling and delivering an increased flow of inspired gas to the person during the inhalation phase, it alleges that Curti can be combined with Levitsky to suggest this combination to one skilled in the art. Again, Applicant submits that this combination is wholly inadequate to render the claimed invention obvious for various reasons and traverses as follows.

As discussed throughout Applicant’s specification, it is a feature of devices and methods according to the invention to limit the flow of gas for inspiration during the exhalation phase in order to enable accurate sampling of expired gases. This is beneficial so as to avoid dilution of a CO₂ sample during the expiratory phase. This is an important goal, as accurate ventilation monitoring is considered a very important benchmark of patient safety protocols according to governing medical guidelines in anesthesia and other medical fields.

While the prior art, as discussed in the Curti and Chua references, may appreciate the need to provide intermittent gas delivery in a variety of circumstances and may indeed describe working ways for achieving and controlling intermittent gas delivery systems, these prior systems do not resolve the problem of providing an integrated solution for simultaneous gas delivery and analysis (sometimes alternatively referred to as “sampling” of expired gases). The structure of the apparatuses and systems recited in all pending claims of Applicant’s application, however, provides such an improved and integrated solution. No teaching is present in any of the prior art references that would lead one skilled in the art to produce the structure recited by the Applicant. The Office Action thereby fails to properly consider the structure recited in all claims when making the present claims both novel and unobvious, and making the present obviousness rejections fatally flawed.

As noted in Applicant’s prior Response and Amendment, Levitsky pertains to a device for collecting expired gases from a patient with the purported benefit of reducing void volume

within expired gas sampling lines (and thus eliminating problems in analysis caused by mixing, dilution collected samples). The Levitsky cannula, as recognized by the Office Action, includes a Y-shaped junction located between the nose and mouth where the tubes of the two nasal prongs and of an oral prong meet with a collection tube. The collection tube thereafter carries the gas to a downstream analyzer. An oxygen delivery tube, adapted to lie across the upper lip of the patient, is also disclosed. This delivery tube has two holes oriented below the nose of the patient intended to direct oxygen flow upward through a screen and to the nostrils of the patient for inhalation. As admitted in the Office Action, Levitsky does not address modulating the flow of delivered gas in any way.

Curti, which the Office Action combines with Levitsky, discloses a split-nare type oronasal device that has a single fluid conduit for introduction up each nostril of the patient. One of the nasal prongs is connected to an oxygen source while the second nasal prong is connected to a gas analyzer. **Importantly, these prongs are not in communication with one another as a matter of a purposeful design decision by Curti.** This separation of the nares in such a cannula is specifically addressed in the background portion of Applicant's specification at page 6, line 10, and within Levitsky at column 2, lines 28-47, and is described in both places as being undesirable in that it does not readily permit automatic control of sampling from various respiratory sites or account for the possibility that one nostril may be completely or partially obstructed compared to the other nostril, leading to poor oxygen delivery or sampling results (or both). Thus, it is important to provide a device that can successfully provide gas delivery to multiple sites while simultaneously sampling expired gases at those multiple sites. **Curti and Levitsky do not, and in fact, cannot, whether alone or in combination, collect expired gases from each nostril and from the mouth for independent and accurate analysis by an analyzer while simultaneously providing gas delivery to these sites, as is specifically required by independent claims 1, 37 and 128.** Furthermore, Chua, which is discussed within Curti relied upon in the Office Action, provides no structure for obtaining a working apparatus or method as recited in a Applicant's present claims.

Levitsky's collected gases are combined nearly immediately into a single expired gas lumen for analysis, while Curti discloses only a single nasal prong for collecting expired gas from a first nostril and a second nasal prong for delivering supplied gas up a second nostril.

The Office Action provides no rationale whatsoever that would modify these two devices to provide an oronasal device that succeeds in collecting expired gases from the three sites and accurately analyzing those expired gases while simultaneously providing gas delivery (such as supplemental oxygen). In this regard, all rejections in the Office Action is deficient.

Contrary to the Office Action's position, there is no rational basis for ignoring Levitsky's distinction, criticism and disassociation of Curti and then combining with Livitsky the very reference he criticized and from which its structure is disassociated. Therefore, not only is there no factual basis for combining these very different references (as described previously and revisited again below), but there is no legal basis for doing so. Indeed, the law conversely precludes such a combination. "When prior art references require selective combination by the court to render obvious a subsequent invention there must be some reason for the combination other than the hindsight gleaned from the invention itself. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 & n.4, 221 USPQ 929, 933 & n. 4 (Fed. Cir. 1984). There must be 'something in the prior art to suggest the desirability, and thus the obviousness, of making the combination'. *Lindemann Maschinenfabric GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984)." An accurate reading of Levitsky will produce no basis for combining its content with that of Curti, but instead will find reasons contradicting such a combination.

As noted previously by the Applicant, the recitation of features that enable independent sampling is an important technological advance over the prior art as such provides various advantages to health care professionals. For example, as recited in dependent claims 10-13, 27, 40, 43, 84-87, and 122 the system can be used to analyze only expired gases from unobstructed nares or to provide separate and/or simultaneous analysis of the gases expired from the nose and the mouth (see, e.g., dependent claims 43-44, 100, 112 and 123).

For these reasons, Levitsky and Curti cannot be considered to teach one skilled in the art how to modify Levitsky to produce Applicant's claimed invention. As such, claims 1, 37 and 128 and all claims being dependent therefrom are patentable over the combination of Levitsky and Curti for these reasons alone.

Applicant also notes that claim 128 is further patentable over the prior art of record in

that it recites that “a lower flow of supplied gas” is provided to the person during an exhalation phase. As explained in Applicant’s specification, a lower baseline rate for inspired gas delivery to the patient during the exhalation phase can optionally be used to provide a generally enriched area of gas for inspiration while not undesirably diluting gases for analysis. The prior art fails to teach this recited feature of the invention, making claim 128 patentable for this additional reason (as well as, for example, dependent claims 32, 39, and 127).

Specifically with regard to claim 57 as presently amended, Applicant submits that this claim recites structural features that further distinguish this claim over the prior art of record. This claim recites that inspired gas is supplied to the person using a oronasal device, and that the inspired gas is delivered through a plurality of holes located “immediately about and partially surrounding the base” of the portions that extend into the nostrils to collect expired gases. As depicted and described in Applicant’s specification at, for example, FIG. 10 and accompanying text, this claimed arrangement of the plurality of fluid outlet holes immediately about the base of each portion that extends into the nostrils can be particularly advantageous. This embodiment of the invention, as taught in the specification, provides for inspired gas flow that is diffuse so as to avoid discomfort and mixing, but which is also sufficiently directed into the nostrils and localized to the area proximate to the nostrils to minimize waste of inspired gas to the atmosphere.

In an apparent attempt to address these claim limitations, the Office Action alleges that, since Levitsky shows a porous “pair of second nasal prongs 102” (See Levitsky, column 9) that serve to provide oxygen delivery to the patient’s nose, this inherently discloses “fluid outlet holes ... located immediately about a base of and partially surrounding” the portions extending into the nares, as is recited by Applicant. A proper reading of Levitsky demonstrates that this is an unsupportable stretch of that reference’s teachings. First, **Levitsky makes clear that the element 102 is a separate prong that extends next to the nasal collection prong 98. Thus, the oxygen delivery pores present in element 102 of Levitsky prong cannot in any way be characterized as “partially surrounding” the base of collection prong 98.** It would be an amazing stretch of the English language to suggest that any part of a first cylinder-shaped object (element 102) placed standing on a surface next to a second cylinder shaped object (prong 98) could be characterized such that the part is

“partially surrounding” a base of the second cylinder. The pores formed in element 102 of Levitsky are located on that element alone, and nowhere else. Without completely redefining the English language, these pores cannot be said to partially surround the collection prong 98 of Levitsky. Further, neither Levitsky or any other prior art of record provides any rationale to produce fluid outlet holes as claimed by the Applicant. Therefore, claim 57 and claims dependent therefrom are allowable over the cited art for this reason alone. Likewise, dependent claims 93 and 105, which depend from independent claims 1 and 37, respectively, are likewise allowable over the prior art.

Furthermore, Applicant notes that various dependent claims recite additional patentable features of these fluid outlet holes relating to further versions of this embodiment of the invention and which the Office Action improperly rejects. For example, dependent claims 94-95 and 106-107 recite limitations wherein these fluid outlet holes are present in an “arc” around the base of the nostril portion to help produce a diffuse flow toward the nostrils. A random (or even uniform) scattering of pores in the surface of element 102 cannot be said to create arc of fluid outlet holes partially surrounding the base of a nostril portion, making these claims clearly allowable over the prior art.

Likewise, dependent claims 96 and 108 recite limitations whereby such partially surrounding fluid outlet holes form a pattern “concentric with” the nostril portion. Again, the structure from Levitsky relied upon in the Office Action clearly lacks this structure.

In light of the above remarks, Applicant respectfully requests reconsideration of all rejections based upon Levitsky and Curti. Applicant respectfully submits that these claims are allowable over the prior art, and appropriate reconsideration is requested.

35 U.S.C. § 103(a) – applying Levitsky, Curti and Chua

Claims 16-20 and 59 were again rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of Chua. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action contends that Chua discloses an oxygen delivery system that utilizes a pressure sensor for detecting whether the person is inhaling, and concludes that the

teachings of Chua could therefore be combined with Levitsky and Curti to produce Applicant's claimed invention. Applicant respectfully submits that Chua does not remedy any of the above deficiencies described immediately above with respect to the combined teachings of Levitsky and Curti, and therefore cannot render the present claims obvious.

Specifically, while Chua may relate to the use of pressure analyzers to determine when a patient is inhaling/exhaling in order to control oxygen delivery, it provides no description of any structure or steps that would permit the simultaneous sampling of expired gases, monitoring of respiratory phase, and oxygen delivery as is claimed by the Applicant. Chua merely describes what it considers to be the optimal manner of timing the increase and decrease of oxygen delivery in an intermittent delivery system. Applicant has not found, nor has the Office Action cited, any teaching present in any of Levitsky, Curti or Chua would lead one skilled in the art to produce Applicant's oronasal structure as claimed. Therefore, in no way can the combination of these three references be considered to render Applicant's claims obvious.

Appropriate reconsideration is thus requested.

35 U.S.C. § 103(a) – applying Levitsky, Curti and Frank

Claims 20-26 and 60-61 were rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of Frank. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action alleges that Frank teaches the use of a humidity sensor and temperature sensor to detect whether the person is inhaling. Even if Frank discloses the use of humidity and temperature sensors to determine when a patient is inhaling/exhaling, that reference does not provide description of any structure or steps that would permit the simultaneous sampling of expired gases, monitoring of respiratory phase, and oxygen delivery, including the particular structure and steps discussed above with respect to the rejections base upon the combination of Levitsky and Curti. Therefore, the combination of these three references cannot be considered to render Applicant's claims obvious.

Appropriate reconsideration is thus requested.

35 U.S.C. § 103(a) – applying Levitsky, Curti and DiBenedetto

Claims 46-49 and 66 were rejected by the Office Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of DiBenedetto. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action alleges that DiBenedetto teaches the use of a microphone to amplify a person's breathing to determine a respiratory phase. Even if DiBenedetto does teach how to use sound to determine a respiratory phase, this does not teach the invention as recited in claims 48, 49 and 66, so applicant respectfully traverses as follows.

Claims 48 and 49 depend from claim 37, and are thus allowable over the art for all the reasons discussed above with respect to the deficiencies of the combined teachings of Levitsky and Curti. Additionally, claim 48 (upon which 49 depends) recites the additional element of an auditory breath sonification device that includes a white noise generator that provides simulated breath sounds. Nowhere does DiBenedetto teach a white noise generator for providing simulated sounds. DiBenedetto uses a whistle-like sensor device for determining whether a patient is inhaling or exhaling according to the sound waves created by the breath stream's interaction with that sensor. It does not determine breathing, and then create simulated breathing sounds as is claimed.

Again, as in the Applicant's several prior filings, Applicant also points out that claim 66 recites the novel and nonobvious addition of a sound lumen to the claimed cannula. The sound lumen connects the person to an auditory device that can create sounds for transmission to the person such that said sound lumen functions as a stimulus channel that carries an auditory prompt to the person. In no way does DiBenedetto discuss transmitting sound to the person for any reason.

Appropriate reconsideration of rejections based in part upon DiBenedetto is thus requested.

35 U.S.C. § 103(a) – applying Connell and Fishman

Claims 33-35/36 and 51/52-54 were rejected by the Office Action under 35 U.S.C. §

103(a) as allegedly being unpatentable over the combination of Levitsky and Curti as further modified in light of Connell/Fishman. Insofar as this grounds for rejection applies to these claims as presently amended, Applicant respectfully traverses.

The Office Action alleges that Connell teaches the monitoring of expired anesthetic gases, such as propofol and that Fishman discloses the use of xenon as a anesthetic gas. Even if these references disclose what is alleged, the references nonetheless fail to provide description of any structure or steps that would permit the simultaneous sampling of expired gases, monitoring of respiratory phase, and oxygen delivery, including the particular structure and steps discussed above with respect to the rejections base upon the combination of Levitsky and Curti. Therefore, the combination of these three references cannot be considered to render Applicant's claims obvious.

Appropriate reconsideration is thus requested.

Allowable Claims

Applicant again thanks the Examiner for the indication of allowable subject matter in this application and notes that several amendments have been made to these claims to retain antecedent basis in light of amendments made to the independent claims. Applicant believes that these amendments should not impact the current allowability of these claims over the prior art.

Request for Examiner Interview

Applicant requests that the Examiner grant the courtesy of a telephonic interview once the Examiner has had the chance to sufficiently review the contents of this paper. Applicant believes that such will most efficiently result in the claims being prepared for immediate allowance as there are clear differences between the embodiments of Applicant's invention and the cited prior art. Thus, the Examiner is respectfully requested to contact the undersigned representative to schedule the telephone interview in the coming weeks.

Application No. 09/878,922
Response and Amendment dated November 28, 2005
Reply to Office Action of July 26, 2005

Conclusion

In view of the foregoing, the Applicant respectfully requests that the Examiner consider the above-noted Response and Amendment when the claims are re-examined on its merits. A timely allowance of the pending claims is requested.

This Response and Amendment is being transmitted concurrently along with a transmittal document serving as a request for extension of time for one month, which is serving as a constructive petition for extension of time. A check is submitted herewith in an amount believed sufficient to cover these fees.

The check is an amount believed sufficient to also cover any additional claims fees due at this time.


If the amount of the check is insufficient to cover the required additional claims and extension of time fees, or is in excess of the required cumulative fee, please charge any necessary fees and/or credit any overpayments to Deposit Account No. 50-1349. Additionally, if there are any other fees due in connection with the filing of this Response and Amendment that are not covered by the enclosed check please charge those other fees to Deposit Account No. 50-1349.

The Examiner is invited to contact Applicant's undersigned representative to expedite prosecution.

Respectfully submitted,

Dated: November 28, 2005

HOGAN & HARTSON LLP
555 13th Street, N.W.
Washington, D.C. 20004
Telephone: 202-637-5600
Facsimile: 202-637-5910
Customer No. 24633

By: 
Celine Jimenez Crowson
Registration No. 40,357

Kevin G. Shaw
Registration No. 43,110